

# Scientific & Regulatory Consultants, Inc.

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## SALLY HAYES

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### PROFESSIONAL SUMMARY

Results oriented, creative, persevering and persistent. Able to manage many projects at the same time in a fast-paced, dynamic environment. Able to communicate concise, accurate, timely, and understandable interpretations of regulatory issues affecting corporate or customer business activities and offer solutions to regulatory hurdles. Over thirty years of increasing responsibility and achievements in the chemical industry.

#### Areas of Expertise:

- ◆ Regulatory Affairs/Compliance
- ◆ Good Laboratory Practices (GLP)
- ◆ Good Manufacturing Practices (GMP)
- ◆ Analyzing Regulatory Impact on Business
- ◆ Technical Presentations
- ◆ Negotiating with Government Agencies
- ◆ Creative Problem Solving
- ◆ Auditing

### PROFESSIONAL EXPERIENCE

SCIENTIFIC & REGULATORY CONSULTANTS, INC., Columbia City, IN

1996-present

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#### **Consultant (Vice-President/Co-Owner)**

Responsible for developing regulatory strategies to obtain regulatory approvals with EPA (Federal and State), FDA, and other Domestic and International Agencies, negotiation with government agencies with respect to labeling and testing requirements, reviewing ads, promotional literature and websites for regulatory compliance, facility auditing for compliance with GLP and GMP.

- Consumer Specialty Products Association, Regulatory Committee Chair; 2004 to 2007
- Presented "Assembling the Package" at the Introduction to Regulatory Toxicology & Registration hosted by CSPA; 11/04
- Presented "How to Submit an Application" at the 6<sup>th</sup> Annual EPA Anti. Div. Program; 06/03
- Customized internal GLP Training Program for a multi-national firm.
- Represented Consumer Specialty Products Association (CSPA) at an EPA Scientific Advisory Panel Meeting.

- Prepared corporate position statement on FQPA and Streamlining issues.
- Advise clients on data compensation.
- Drafted scientific and regulatory portion of an Initial Public Offering (IPO).
- Designed and coordinated the CSPA Antimicrobial Registration Workshop.
  - “Application... to Registration...and Beyond”, 1999, in association with US EPA.
- Prepare responses to proposed regulations and government policies
- Designed and coordinated the CSPA Antimicrobial Registration Workshop.

HUNTINGTON LABORATORIES, INC., Huntington, IN

1988-1996

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**Regulatory Affairs Manager**

Responsible to President for the development, implementation, and analysis of regulatory programs, and procedures to ensure compliance with State, Federal, and International regulations. To provide regulatory strategy and leadership to management, scientific, and technical staff.

- Developed regulatory strategies to obtain regulatory approvals with EPA, FDA, and other Domestic and International agencies of over 100 EPA registrations, one new drug and six medical devices.
- Negotiated with the various government agencies with respect to labeling and testing requirements to obtain and maintain registrations.
- Reviewed, analyzed and advised management on proposed and final regulations for impact on corporate and customer business.
- Prepared and conducted seminars for sales representative and customers on current regulatory and legislative issues.
- Presented at ISSA Pesticide Labeling Workshop.
- Implemented internal GLP program as a member of Good Laboratory Practices (GLP) team. Resulted in Council for Antimicrobial Quality Certification in 1995.
- Chair of the CSMA EPA/FDA Jurisdictional Task Force. Presented industry position at FDA Panel Meeting.
- Audited contract laboratories, contract manufacturers, and corporate branches to ensure compliance with regulatory requirements
- Directed staff in areas such as State Registrations, USDA, SARA Title III, OSHA Right-To-Know, Domestic and International Shipping, and VOC Regulations.
- Promoted in 1989.

THE FULLER BRUSH COMPANY, Great Bend, KS

1977-1988

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**Supervisor Quality Control Lab**

Responsible for day-to-date quality of \$20MM Chemical line. Interfaced and resolved problems involving contract suppliers, vendors, manufacturing, marketing groups, purchasing, and production control. Wrote training program for OSHA Hazard Communication Standard, trained over 500 employees and monitored on-going program.

- Research and Development Chemist – aerosols, personal care, and cleaning supplies. Developed product and package stability, established specifications and followed through manufacturing start-up.

- Quality Control Chemist-inspected all incoming raw materials for compliance to standards. Checked batches and determined adjustments needed.
- Promoted 1979 and 1983.

### **EDUCATION**

Bachelor of Science in Secondary Education, Kansas State University, Manhattan, KS  
Undergraduate Business Courses (30 hours), Fort Hays State University, Hays, KS

### **PROFESSIONAL AFFILIATIONS & CERTIFICATIONS**

Regulatory Affairs Professional Society (RAPS)

### **CORPORATE PROFESSIONAL AFFILIATIONS**

American Chemistry Council (ACC)  
British Association for Chemical Specialties (BACS)  
Consumer Specialty Products Association (CSPA)  
International Association for Food Protection (IAFP)  
International Sanitary Supply Association (ISSA)  
National Spa & Pool Institute (NSPI)  
Personal Care Products Council (PCPC; formerly CTFA)

### **PROFESSIONAL DEVELOPMENT**

#### **REGULATORY CONFERENCES, SEMINARS AND TRAINING**

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##### **EPA**

Greening Operation Series: Regulatory Update-Antimicrobial Labeling Update from the EPA; 07/09  
Pesticide Program Dialogue Committee Fall Meeting; 10/07  
The Globally Harmonized System of Classification and Labeling of Chemicals; 10/06  
Seventh Antimicrobial Workshop; 11/05  
Pesticide Registration Improvement Act: Workshop for Stakeholders; 03/04  
EPA Workshop; 06/03  
National Meeting on the Regulation of Antimicrobial Pesticide Workshops; 2003, 2000, 1999, 1998, and 1997

##### **CSPA**

Mid-Year and Annual Meetings; 1988 – present  
Understanding Pesticide Data Requirements and Compensation; 03/10  
To amend or not to amend? Webinar; 10/09

CSPA/ISSA Ninth Antimicrobial Workshop; 10/09  
CSPA Workshop on Importing Pesticide Products; 06/08  
Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Potential Modifications to HazCom Standard; 10/06  
International Affairs Conference/CSPA; 10/06  
Introduction to Regulatory Toxicology & Registration hosted by CSPA (Speaker and attendee); 11/04  
CSPA Meeting with California DPR – Streamlining; 08/03  
CSPA Meeting with California DPR – Mill Assessment; 12/02  
Toxicology 101; 2002  
Antimicrobial Registrations Workshop “Application...To Registration...And Beyond”; 1999  
Good Laboratory Practices Seminar; 1992

**West Coast Quality Training Institute (Pacific Rim Consulting)**

“Practical Approach” Seminar; Advanced GLP Issues; 07/09  
Good Laboratory Practices for Technical Staff; 03/06  
Quality Assurance in GLPs; 09/02  
Introduction to EPA/FDA/OECD Good Laboratory Practices; 09/02

**Executive Conferences; webinars**

Validation and Performance Testing of Antimicrobial Technologies; 06/09

**Wright Alliance, LLC.**

Biocide Product Directive and REACH; 08/08

**Regulatory Affairs Professional Society (RAPS)**

Recall or Not to Recall; 02/09  
Natural Health Product (NHP) Licensing in Canada: Moving Forward-Updates, Initiatives and Challenges; 10/09

**Canadian Consumer Specialty Products Association (CCSPA)**

Annual CCSPA/Federal Government Interface; 05/08, 04/06

**California EPA**

BPPD Meeting; 09/09  
VOC Workshop; 08/06

**FDC Services LLC**

CGMP/QSR Training Program; 06/08

**Quality Is Learned**

Current Good Manufacturing Practice Regulations; 21 CFR Parts 210 & 211; 02/06

**Chemical Producers & Distributors Assoc./International Sanitary Supply Association**

Confidential Statement of Formula and Other Emerging Issues; 06/03  
Reporting of Adverse Effects-FIFRA 6(a)(2); 06/02

**California Department of Registration**

Antimicrobial Registration Workshop; 10/02

**Clinical Device Group, Inc.**

The Successful 510(k); 06/07

**Western Crop Protection Association (WCPA)**

California Pesticide Regulations Course; 08/95

**Health Canada**

Canadian Pesticide Regulation Course; 1998

**New York State Department of Environmental Conservation**

Pesticide Producers Regulatory Workshop; 06/02

**American Management Association (AMA)**

Quality Control: Meeting the New Competition; 1987

**Hazardous Materials Advisory Committee/Dangerous Government Services Institute (HMAC/GSI)**

Transportation of Hazardous Materials and Goods Advanced Course; 1995

**Northeast Indiana Quality Network**

Benchmarking Your Competitor; 1996

**Target Research Associates (Dr. Robert McCormack)**

The Mechanics of Preparing INDS & NDAs and FDA regulations; 1998

**Center for Environmental & Regulatory Information System-Purdue University**

National Pesticide Information Retrieval System Training; 1998

**Center for Professional Advancement**

Aerosol Technology Course; 06/82

**Varian Associates**

Maintenance and Troubleshooting of the 3700 Gas Chromatograph; 10/83

**American Bar Association-Committee on Pesticides, Chemical Regulations, and Right-To-Know**

Antimicrobial Pesticides-Regulation of Innovative and Unique Products; 05/04

## SAFETY CONFERENCES, SEMINARS AND TRAINING

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### **The University of Toledo**

In-Plant Industrial Chemical Spill Response Course; 04/89

## OTHER PROFESSIONAL CONFERENCES, SEMINARS AND TRAINING

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### **Gladieux Consulting**

What Your Words Say About You and Your Team: Business Writing; 04/09

Better Business Writing/Documentation; 05/06

Powerful Presentation Skills; 08/02

Better Business Writing; 08/02

Time Management; 08/02

### **Association of Official Analytical Chemists (AOAC)**

How to Testify as an Expert Witness; 1992

## **PUBLICATIONS & PRESENTATIONS**

### PUBLICATIONS

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Cozad A, Hayes S. Regulatory Strategy and EPA Requirements for the Corrosion Control Using Regenerative Biofilms (CCURB) Product. EPRI, Palo Alto, CA: 2004. 1009465.

### PRESENTATIONS

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Presented "How to Submit an Application" at the 6<sup>th</sup> Annual EPA Antimicrobial Division Program; 06/03